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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,729	10/29/2003	Scott Freeberg	279.652US1	6340

21186 7590 01/12/2007
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EXAMINER

HOLMES, REX R

ART UNIT	PAPER NUMBER
	3762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,729	FREEBERG, SCOTT	
	Examiner	Art Unit	
	Rex Holmes	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 October 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-55 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/31/06</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-37 and 46-55 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

2. The indicated allowability of claims 38-45 is withdrawn in view of the newly discovered reference(s) to Daum et al. (U.S. Pat. 7,101,339) and Daum in view of Hine et al. (U.S. Pat. 7,142,919). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-6, 9-11, 13-16, 19-20, 23-26, 28-34, 38-40, 44-46, 51-53 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Daum et al. (U.S. Pat. 7,101,339 hereinafter "Daum") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Daum in view of Hine et al. (U.S. Pat. 7,142,919 hereinafter "Hine").

6. The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

7. Regarding claims 1-4, 6, 9-11, 14, 16, 25-26, 29-32, 38-40, 44 and 51, Daum discloses a system that includes a current generator (Col. 2, l. 1), multiple chamber lead placement (Col. 2, ll. 53-54) of paired electrode leads (Col. 2, l. 64), a processor adapted to identify the relationship between impedances and to monitor the first, second, and possibly third signal (Col. 1, l. 67 & Col. 2, ll. 3-11), a filter to determine

frequencies in the ventilation band (Col. 5, ll. 34-36), a therapy output to provide a pacing pulse (Col. 4, ll. 20-21), a generated ventilation signal (Col. 2, ll. 3-11),

8. Regarding claims 5, 19-20, 28, 33-34, 46 and 52, the system, device and method of Daum is included in a pacemaker/defibrillator and although not explicitly stated, pacemakers and defibrillators inherently have a pulse generator and therapy circuitry.

9. Regarding claims 13 and 15, the system of Daum provides for both left and right heart stimulation and impedance sensing, and thus is inherently creating a transthoracic current field (Col. 2, ll. 50-67).

10. Regarding claim 45, Daum discloses comparing signals and providing a resulting signal that is a correlate of the selected signals (Col. 6, ll. 58-67 & Col. 7, ll. 1-5).

11. Regarding claims 53 and 55, Daum discloses that the system and method can be used internally, externally, or with any type of cardiac rhythm management system and is capable of being configured to a thorax (Col. 2, ll. 50-61). Daum further discloses that the system can utilize cellular telephones or radios (Col. 5, ll. 2-5).

12. Daum discloses the claimed invention as disclosed above, but Daum does not specifically disclose the delivery of a pacing therapy, or transthoracic impedance sensing. However, Hine discloses fault tolerant multiple electrode lead systems that determines transthoracic impedance measurements and utilizes the impedance measurements to configure the delivery of the pacing and therapy stimulus (Fig. 13; Col. 1, ll. 20-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the impedance sensing system of Daum with the therapy system that is based on hemodynamic parameters as taught by

Hine since such a modification would provide a hemodynamic based pacing system that would be able to pace during activities and increased respiration.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 7-8, 12, 17-18, 21-24, 27, 35-37, 41-43, 47-50, and 54 are rejected under 35 U.S.C. 103(a) as being obvious over Daum in view of Hine et al. (U.S. Pat. 7,142,919 hereinafter "Hine").

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

16. Daum discloses the claimed invention as discussed in detail above, but Daum fails to disclose an impedance monitoring system that includes an activity sensor. However, Hine discloses a lead system that utilizes impedance, transthoracic impedance, and acceleration in variable pacing (Col. 6, ll. 1-67). Hine, further discloses the use of two accelerometers with intersecting axis's (Col. 23, ll. 43-56; Col. 26, ll. 15-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the impedance monitoring system as taught by Daum, with the impedance and acceleration system as taught by Hine, since such a modification would provide the impedance system with more accurate way to determine activity for providing improved pacing during physical activity.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bradley et al. (U.S. Pat. 6,931,281); Combs et al. (U.S. Pat. 6,512,949); Combs et al. (U.S. Pat. 5,957,861).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit 3762



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